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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,764	09/30/2003	Hoa Duc Nguyen		6271

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HIGH STANDARD PRODUCTS CORPORATION
SUITE 225
14441 BEACH BLVD.
WESTMINSTER, CA 92683

EXAMINER

GAKH, YELENA G

ART UNIT	PAPER NUMBER
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1797

MAIL DATE	DELIVERY MODE
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04/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/675,764

Applicant(s)

NGUYEN ET AL.

Examiner

Yelena G. Gakh, Ph.D.

Art Unit

1797

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 25 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-40, 42, 44 and 45 is/are pending in the application.
- 4a) Of the above claim(s) 30, 32 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-29, 31, 33-35, 37-40, 42, 44 and 45 is/are rejected.
- 7) ☒ Claim(s) 26-28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 January 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 09/30/03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Amendment filed on 01/25/08 is acknowledged. Claims 41 and 43 are cancelled. Claims 25-40, 42 and 44-45 are pending in the application. Claims 30, 32 and 36 are withdrawn from consideration as directed toward non-elected species. Claims 25-29, 31, 33-35, 37-40, 42 and 44-45 are considered on merits.

Response to Amendment

2A. An examination of this application reveals that applicants are unfamiliar with patent prosecution procedure. While inventors may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicants are advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

A listing of registered patent attorneys and agents is available on the USPTO Internet web site <http://www.uspto.gov> in the Site Index under "Attorney and Agent Roster." Applicants may also obtain a list of registered patent attorneys and agents located in their area by writing to the Mail Stop OED, Director of the U. S. Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450.

B. The amendment filed 01/25/08 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: essential amendments on pages 6-10, 12-15, and 19.

Applicant is required to cancel the new matter in the reply to this Office Action or is advised to file Continuation-in-Part.

C. The examiner modifies rejections in light of the amendment.

Information Disclosure Statement

3. The listing of references in the specification (pages 25-26) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other

information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

4. Claims 26-28 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. From claim 25 it is clear that mass spectrometry is performed with the stable isotope labeled internal standard, rather than radioactive isotope labeled internal standard, and therefore the recitation of claim 26 does not further limit the method of the parent claim. Claim 27 recites all possible carboxylic acids, and therefore does not further limit the structure of the carboxylic acids recited in the parent claim. The same is true for claim 28, which recites conventional esters for carboxylic acids. If the Applicants prefer to use structural formulas for the recited compounds, they should recite them in the parent claim.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 25-29, 31, 33-35, 37-40, 42 and 44-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of **quantification** of the **known** carboxylic acid, does not reasonably provide enablement for the method of **identification** of an **unknown** carboxylic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. There is no way for a practitioner in the art to perform the method recited in the claims directed to identification of unknown carboxylic acids, because step a) recites synthesizing labeled carboxylic acid ester by reaction of an

authentic sample of carboxylic acid, which assumes that the carboxylic acid is known, i.e. identified.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 25-29, 31, 33-35, 37-40, 42 and 44-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 recites "a method of one step synthesis of stable isotope labeled internal standards and additional chemical reaction", which is an unclear expression. What type of "additional chemical reaction" the claim recites? The preamble of the claim is quite confusing. From the body of the claim it is not apparent, as to what is the "authentic sample of carboxylic acid"? Is this a sample of **said** carboxylic acid (the preamble of the claim should recite "**a** carboxylic acid")? To the examiner's understanding, the authentic sample of the carboxylic acid is a different sample from the one under analysis, i.e. the one recited in the preamble of the claim. In step c) it is not clear, as to how the condition "wherein there is no reaction of said labeled carboxylic acid ester with said derivatizing reagent" is fulfilled? Should the reaction conditions be optimized to meet this requirement? Or this is an inherent feature of the synthesis? From step d) it is not quite apparent, as to what should the carboxylic acid ester and the internal standard be extracted from? It looks from the preamble of the claim that the sample comprises an aqueous solution of the carboxylic acid, and therefore it is not clear, as to why the ester should be extracted from its aqueous solution?

From claims 39-40 it is unclear, as to whether internal standards are separately obtained for each known carboxylic acid, and then combined with the sample? The recitation of the claims is not clear.

Claim 40 does not appear to recite any active step. The expression "can be synthesized" is not an active step of the method.

The recitation of amended claim 44 is just unclear. What does it mean?

Claim 45 recites a Markush group in an improper format. The Applicants are recommended to use MPEP Chapter 2173.05(h) for proper recitation of Markush group.

Response to Arguments

9. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection. However, the examiner would like to make several notes to the Applicants' remarks.

The examiner advises the Applicants to secure the services of a registered patent attorney or agent to prosecute the application, as it was indicated above.

The Applicants' Remarks should not include a copy of the Office action to which the remarks are made. This makes the clerical processing of the incoming documents confusing.

The Applicants cannot amend the specification. Providing extensive amendment to the specification always raises the issue of new matter. In the previous Office action the examiner suggested the Applicants to provide one illustrative mass spectrum, rather than introducing significant amendment in the disclosure. If the Applicants choose to have amended specification, they should file Continuation-in-Part.

Regarding IDS references - the Applicants should not provide references in IDS form that were cited by the examiner and sent to the Applicants (e.g. Husek's article in J. Chromat. B., 1998). Furthermore, if the Applicants want the examiner to consider additional references provided in the specification, IDS form with listing all these references and NPL references themselves should be provided to the examiner.

While the examiner withdraws rejections over the prior art, the issues of new matter, along with enablement and unclarity issues, remain in the application.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yelena G. Gakh/
Primary Examiner, Art Unit 1797

4/23/2008